APR 19 2004 hereby certify that this correspondence is being deposit

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Thereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: <u>PATENT</u>

Attorney Docket No.: 017516-007400US

Mail Stop Petition

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

on 17 1 1 1 , 2009

TOWNS END and TOWNSEND and CREW LLP

By: Sign Hoover

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APR 2 2 2004

OFFICE OF PETITIONS

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

PHILIP S. GREEN

Patent No.: 5,808,665

Issued: September 15, 1998

For: ENDOSCOPIC SURGICAL

INSTRUMENT AND METHOD OF USE

Customer No.: 20350

PETITION TO DIRECTOR FOR QUESTIONS NOT SPECIFICALLY PROVIDED FOR UNDER 37 C.F.R. § 1.182

**Mail Stop Petition** 

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.182, Applicants are filing this petition for questions not specifically provided for in the regulations to invoke the supervisory authority of the Director. Please deduct the requisite fee, pursuant to 37 C.F.R. § 1.17(h), of \$130 from deposit account 20-1430, and deduct any additional fees or credit any excess fees associated with this petition to such deposit account.

04/21/2004 ANDNDAF2 00000070 201430 08709965

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Phillip S. Green Patent No.: 5,808,665

#### STATEMENT OF FACTS

A patent term extension application of U.S. Patent No. 5,808,665 was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration ("FDA") approval of the da Vinci<sup>®</sup> Robotic Surgery System. A Final Determination of Ineligibility was mailed from the U.S. Patent and Trademark Office ("USPTO") on November 14, 2001. A timely request for reconsideration of the final determination of the patent term extension of the '665 patent was filed on January 9, 2002, a copy of which is attached hereto as Exhibit A. In April of 2002, Applicants were copied<sup>1</sup> on a letter by Karin Ferriter, Senior Legal Advisor for the Office of Patent Legal Administration and Office of the Deputy Commissioner for Patent Examination Policy of the USPTO, to David T. Read, Acting Director Health Assessment Policy Staff, CDER of the FDA. This letter, a copy of which is attached hereto as Exhibit B, forwards Applicants request for reconsideration to the FDA for comment in order to assist the USPTO to reconsider the final determination of ineligibility.

To date, Applicants have not received any further official correspondence from the USPTO or FDA regarding our request for reconsideration.

#### **ACTION REQUESTED**

Applicants filed the reconsideration request over two years ago with the USPTO and to date have not received any determination regarding this request which was filed on January 9, 2002. As such, Applicants request that the Director invoke supervisory authority over the Offices of Patent Legal Administration and/or the Deputy Commissioner for Patent

<sup>&</sup>lt;sup>1</sup> Sally Yeager of Alcon Laboratories Inc. was copied in error.

Examination Policy of the USPTO to move this reconsideration request forward and to advise us of the status of this request.

Respectfully submitted,

Nena Bains

Reg. No. 47,400

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Fighth Floor

Two Embarcadero Center, Eighth Floor San Francisco, California 94111-3834

Tel: 415-576-0200 Fax: 415-576-0300 Attachments: Exhibit A

Exhibit A
Exhibit B

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION Filing Acknowledgment

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION Filing Acknowledgment

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Mailing Date:	January 9, 2002	Serial No.	08/709,965		
File No.:	17516-007400	Attorney:	MDB/NB/kab		
Applicant:	GREEN, Phillip S.				
Title:	Endoscopic Surgica Instrument and Method of Use				
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# REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION Filing Acknowledgment

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Mailing Date:	January 9, 2002	Serial No.	08/709,965	
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Fee Transmittal

Petition For Extension of Request for Reconsideration For Patential **Extension** 

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DUE DATE: January 14, 2002 Express Mail Label No. EL140089321US

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			Applic	ation Number	08/709,965	
	SMITTAL		Filing	Date	September 9, 1996	
F	ORM		First N	lamed Inventor	GREEN, Phillip S.	
(to be used for all correspondence after initial filing)			Group	Art Unit		
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Total Number of Pages	in This Submission	7	Attorn	ey Docket Number	017516-007400US	
		ENCL	OSURES	(check all that apply)		
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and Individual name	Mark D. Barrish	. /	1 ,	Reg. No	o. 36,443	
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Date	<i>V</i> January 9, 2002					
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I hereby certify that th Address" service unde	Express Mail Label: EL140089321US  I hereby certify that this correspondence is being deposited with the United States Postal Service with "Express Mail Post Office to Address" service under 37 CFR 1.10 on this date January 9, 2002 and is addressed to:  Assistant Commissioner for Patents, Washington, D.C. 20231					
Typed or printed name	e Daniel Mirano	la	<i>a</i>			
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Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231. PA 3194291 v1

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		Complete If Known				
FEE TRANS	MIIIAL	Application Number	08/709,965			
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		First Named Inventor	GREEN, Philip S.			
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Applicant claims small entity status.  See 37 CFR 1.27	113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action
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Name (Print/Type)	Mark D. Barrish	Registration No. (Attorney/Agent)	36,443	Telephone	650-326-2400
Signature	1/2	252		Date	January 9, 2002

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Approved \*

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PA 3194286 v1

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Date of Deposit January 9, 2002

TTC Docket No. 017516-007400US

I hereby certify that this is being deposited with the United States Postal Service "Express Mail Post Office to Address" service under 37 CFR 1.10 on the date indicated above and is addressed to:

> BOX PATENT EXTENSION Commissioner for Patents Washington, D.C. 20231

By: Daniel Miranda

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

Phillip S. Green

Patent No.:

5,808,665

Issued:

September 15, 1998

Title: ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD FOR USE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Hon. Commissioner of Patents and Trademarks

Box: Patent Extension Washington, D.C. 20231

Sir:

Applicants respectfully request reconsideration for a patent term extension of U.S. Patent No. 5,808,665. A patent term extension request was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration (hereinafter "FDA") approval of the da Vinci<sup>TM</sup> Robotic Surgery System. A Final Determination of Ineligibility (hereinafter "Determination") was mailed from the Patent Office on November 14, 2001.

Dismissal of the application for the subject patent term extension was apparently based on the determination by the Commissioner of Patents and Trademarks (hereinafter "Commissioner") that the da Vinci<sup>TM</sup> System underwent regulatory review under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (hereinafter "FFDCA"). Determination, page 2. However, as properly determined by the FDA, the da Vinci<sup>TM</sup> system was subjected to a regulatory review period as defined by 35 U.S.C. §156(a)(4), including regulatory review under section 515 of the FFDCA. FDA letter dated October 2, 2001.

Phillip S. Green

Patent No.: 5,808,665

Page 2

The regulatory review of the da Vinci<sup>TM</sup> System was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k). As the da Vinci<sup>TM</sup> System was subjected to regulatory review under section 515, Applicants are entitled to a patent term extension. Per 35 U.S.C. §156(d)(2), the Secretary of Health and Human Services is responsible for determining the Regulatory Review Period for medical devices, and this matter was properly referred to the FDA. In a preliminary eligibility decision, the FDA informed the Commissioner that a "review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4)." Id (Emphasis added).

Reviewing the language of the statute, 35 U.S.C. § 156(a)(4), requires that, "the product has been subject to a regulatory review period before its commercial marketing or use." For medical devices, the term "regulatory review period" is defined in § 156(g)(3)(B) as follows:

- (i) the period beginning on the date a clinical investigation on human involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
- (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(Emphasis added). Therefore, within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials and ends on approval under the "Act," i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5.

The FDA correctly verified that Applicants meet the statutory requirements for a regulatory review period under the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B). *Id.* Specifically, Applicants began their first clinical investigations on humans on July 27, 1998. On January 17, 1999 Applicants submitted a section 510(k) application

Phillip S. Green
Patent No.: 5,808,665

Page 3

#K990144 to the FDA seeking laparoscopic approval for its da Vinci<sup>TM</sup> System. On May 19, 1999, the FDA reclassified the da Vinci<sup>TM</sup> System into a class III device requiring Pre-Market Approval (hereinafter "PMA") under section 515. Applicants complied with the FDA mandated reclassification by (a) submitting a complete PMA application #P990079 on November 18, 1999 based on the same clinical data gathered during its earlier human clinical investigations, and (b) requesting that the FDA approve the da Vinci<sup>TM</sup> System under section 515 for laparoscopic procedures. The FDA accepted the PMA application for filing on November 29, 1999. On May 22, 2000, the FDA again reclassified the da Vinci<sup>TM</sup> System so that its corresponding PMA application #P990079, which had been reviewed for over a year under section 515, was reverted back to a 510(k). On July 11, 2000, the FDA approved the 510(k) application #K990144, with the submission date marked as November 18, 1999, the date the PMA application #P990079 under section 515 was submitted to the FDA.

As a final matter, Applicants gratefully acknowledge the Patent Office's correct determination that the Patent Term Extension request was timely filed. Determination, page 1. The FDA communication raised the issue as to whether the application was timely filed within the sixty-day (60) statutory period under 35 U.S.C. § 156(d)(1). FDA letter dated October 2, 2001. While the FDA often possesses information which is not readily available to the Commissioner, the Commissioner has primary responsibility for the eligibility determination. See M.P.E.P. § 2756. The Commissioner correctly determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms. Determination, page 1. The date of product approval was July 11, 2000. The present patent term extension application was filed on Monday, September 11, 2000. Sixty days after the approval date of the product was Saturday, September 9, 2000. 35 U.S.C. § 21(b) states that

When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

As Monday, September 11, 2000 was the next succeeding business day following the last day (Saturday, September 9, 2000), the application was timely filed.

As the FDA has verified that the present application satisfies the statutory

Phillip S. Green
Patent No.: 5,808,665
Page 4

requirements for a regulatory review period under 35 U.S.C. § 156(a)(4) and the Commissioner has determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms, the last day of said sixty-day (60) period being September 11, 2000, the present application qualifies for a patent term extension. For the foregoing reasons, reconsideration and granting of Applicants application for patent term extension is respectfully requested.

Respectfully submitted,

David M. Shaw

Reg. No. 38,688 Chief Patent Counsel Intuitive Surgical, Inc.

Tel: (650) 237-7000 Fax: (650) 526-2060

PA 3191866 v1

04/24/2002 12:26 6508596420 04/23/2002 13:43 PAX 817 861 4610

SRI PATENT OFFICE R&D COUNSEL

02 PAGE 1/21002



United States Patent and Trademark Office

COMMISSIONER FOR PORTEIN AND TRADEMARK

David T. Read Acting Director Health Assessment Policy Staff, CDER Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852

9 2002

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APR 1 5 2002

Dear Mr. Read:

SSY

A determination was made that U.S. Patent No. 5,808,665, which claims the medical device da VINCITE System, is incligible for patent term extension under 35 U.S.C. §.156 because the medical device da VINCITE system underwent regulatory review under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA), not under section 515 of the FFDCA and, as a result, was not eligible for patent term extension. See Manual of Patent Examining Procedure, Section 2751, page 2700-14, Eighth edition (August 2001), citing In re Nitinol Medical Tecimologies Inc., 17 USPO2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). See also Baxter Diagnostics v. AVI, Scientific Corp., 798 F. Supp. 612, 619-620; 25 USPO2d 1428, 1434 (1992)(Congress intended only Class III medical devices to be eligible for patent term extension).

In reply, on January 9, 2002, applicant explained that the regulatory review period of the product was as required by 35 U.S.C. 156(g)(3)(B), because regulatory review was conducted under Section 515 of the FFDCA, and the subsequent approval under the Act, albeit under section 510(k) of the Act, did not diminish the patent's eligibility for patent term extension. Applicant relies upon the Food and Drug Administration's prior conclusion that applicant met the statutory requirements for regulatory review in support of their argument that the patent is eligible for extension.

FDA is requested to comment upon the reply (a copy of which is enclosed) in order to assist the U.S. Patent and Trademark Office reconsider the final determination of ineligibility.

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail:

Commissioner for Patents

Box Patent Ext.

Washington, D.C. 20231

By FAX:

(703) 872-9411

Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159. E-mail inquiries should be directed to Karin. Tyson@uspto.gov.

torre Karin Ferriter

Karin Femilia Senior Legal Advisor Office of Patent Legal Advinistration Office of the Deputy Commissioner for Patent Examination Policy

Sally Yeager Alcon Laboratories Inc. R&D Counsel Q-148 6201 South Freeway Forth Worth TX 76134

PAGE 03

04/24/2002 12:26 6508596420

SRI PATENT OFFICE

04/23/2002 13:44 FAX 817 851 4810

RAD COUNSEL

Ø 003

#### United States Patent [19]

Greca

121 Patent Number:

5,808,665

[45] Date of Patent:

Sep. 15, 1998

[54] ENDOSCOPIC SURGECAL INSTRUMENT AND METHOD FOR USB

[75] Inventor: Philip S. Green, Redwood City, Calif.

[73] Assignon: SRI International, Monlo Park, Calif.

[21] Appl. No.: 709,965

Sep. 9, 1996 [22] Flied:

Related U.S. Application Data

[65] Continuation of Ser. No. 823,932, Jun. 21, 1992, sha \_ YEARN 7/LS [33] Int. CL. . 348/65; 600/101 U.S. CI 348/159, 207; 600/101, 109; 901/1, 2, 9, 30, 33, 34, 36; EI04N 7/18 Field of Sourch

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Year	~~~	

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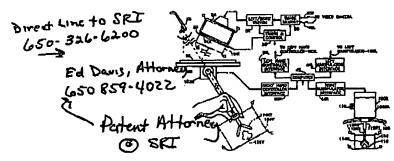
#### (List continued on next page.)

Primary Examiner—Richard Lot Attorney, Agent, or Pirms—Townsend and Townsend and Crew LLP

ABSTRACT [57]

A taleoperator system with talespressors is shown which includes right and left hand commollers (72R and 72L) for control of right and left hand commollers (24R and 24L) through use of a sorvemechanism that includes computer (42). The taleoperator system comprises a endoscope surgical instrument comprises a control servementations which operates an insertion section. The insertion section comprises a forearm, a write and an end effector. The and affector is a modified surprised instrument couprises upon as retractors, electrosmorpical. surgical instrument such as retractors, electrosurgical curious, electroscopical compulation, forceps, needle builders, eciseous, blades and irrigators. The control section contains motion and linkages which operate the insertion section with five or more degrees of freedom. The control section inserts, private and retakes the fibratum with four degrees of freedom about axes that all intersect adjacent a small incifreedom about seeks can all memorare appears a small mea-sion through which the insection section is introduced to the parient. The control section also pivots the wrist with at least one degree of freedom relative to the forearm and operates the end effector. The surgical manipulator provides superior flexibility in performing endocuring procedures compared to standard rigid endoscopic instruments and is adapted for teleoperator control.

32 Cinitas, 9 Drawing Sheets



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SRI PATENT OFFICE

R&D COUNSEL

PAGE 04 2001



6201 South Freeway Fort Worth, Texas 76134-2099 (817) 293-0450

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April 23, 2002

INTELLECTUAL PROPERTY LAW AND R&D COUNSEL

-T	-TELEFAX TRANSMISSION COVER SHEET-						
TO:	Ed Davis						
NUMBER:	650-859-6420						
FROM:	Sally Yeager						
RE: U.S. Patent No.	5,808,665						
MESSAGE: Mr. Dav	vis,						
Per our conversation, believe I was copied o	here is a fax of the letter I was copied on from the U.S.P.T.O. I on error.						
	Sally Yeager						
	Assistant General Counsel,						
	Alcon Research, Ltd.						
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PAGE 01

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Robert Dennis Intritive Sugreat

Date:

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Edward E. Davis

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US Patent 5, 808, 665

Reguest for Term Extension -

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DHU/ PTO/SB/21 (08-03)

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#### **TRANSMITTAL FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This

Application Number	08/709,965
Patent Number	5,808,665
Issue Date	September 15, 1998
First Named Inventor	GREEN, PHILIP S. CEIVED
Art Unit	APR 2 2 2004
Examiner Name	OFFICE OF PETITIONS
Attorney Docket Number	017516-007400US

Submission				017516-00740005					
		ENCLOSUR	ES (Check all that appl	y)					
Fee Transmittal	Form	Drawing(s)		After Allowance Communication to Group					
Fee Attach	ed	Licensing-relation	ted Papers	Appeal Communication to Board of Appeals and Interferences					
Amendment/Rep	oly	Petition		Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)					
After Final		Petition to Cor Provisional Ap		Proprietary Information					
Affidavits/d	eclaration(s)	_	ney, Revocation respondence Address	Status Letter					
Extension of Tim	ne Request	Terminal Discl	aimer	Other Enclosure(s) (please identify below):					
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☐ Information Disc	losure Statement								
Certified Copy of Document(s)	Priority	Remarks	The Commissioner is Account 20-1430.	authorized to charge any additional fees to Deposit					
Response to Mis	-								
	to Missing Parts FR 1.52 or 1.53								
	SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT								
Firm or									
Individual	Nena Bains		Reg. N	0. 47,400					
Signature	Signature								
Date	Date 4 15 04								
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Typed or printed name	Gigi Hoover		
Signature	Dig Hoover	Date	April 15, 2004

PTO/SB/17 (10-03) FEE TRANSMITTAL Complete if Known 08/709,965 **Application Number** for FY 2004 5,808,665 Patent Number September 15, 1998 Issue Date GREEN, PHILIP SRECEIVED Effective 10/01/2003. Patent fees are subject to annual revision. First Named Inventor Applicant claims small entity status. See 37 CFR 1.27 **Examiner Name** Art Unit 017516-007400 OFFICE OF PETITIONS TOTAL AMOUNT OF PAYMENT (\$)

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	METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)					
Check	Credit Card Money Order Other None	3. ADD	ITIONAL F				
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Deposit Account	20-1430	Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
Number	20 1400	1051	130	2051	65	Surcharge - late filing fee or oath	
Deposit		1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
Account	Townsend and Townsend and Crew LLP	1053	130	1053	130	Non-English specification	
Name		1812	2,520	1812	2.520	For filing a request for reexamination	
	uthorized to: (check all that apply)  i) indicated below	1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
Charge any	additional fee(s) or any underpayment of fee(s)	1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
_ ,	i) indicated below, except for the filing fee titled deposit account.	1251	110	2251	55	Extension for reply within first month	
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	FEE CALCULATION						
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Large Entity	Small Entity	1254	1,480	2254	740	Extension for reply within fourth month	
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1.7	Code (\$) 2001 385 Utility filing fee	1255	2,010	2255	1,005	Extension for reply within fifth month	
	, ,	1401	330	2401	165	Notice of Appeal	
	2002 170 Design filing fee 2003 265 Plant filing fee	1402	330	2402	165	Filing a brief in support of an appeal	
	2004 385 Reissue filing fee	1403	290	2403	145	Request for oral hearing	
	2005 80 Provisional filing fee	1451	1,510	1451	1,510	Petition to institute a public use proceeding	
	SUBTOTAL (1) (\$)	1452	110	2452	55	Petition to revive – unavoidable	
	000101A2(1)	1453	1,330	2453	665	Petition to revive – unintentional	
2. EXTRA CL	AIM FEES FOR UTILITY AND REISSUE	1501	1,330	2501	665	Utility issue fee (or reissue)	
	Fee from	1502	480	2502	240	Design issue fee	
_	Extra Claims below Fee Paid	1503	640	2503	320	Plant issue fee	
Total Claims	-" =	1460	130	1460	130	Petitions to the Commissioner	130
Independent Claims		1807	50	1807	50	Petitions related to provisional applications	
L. Multiple		1806	180	1806	180	Submission of Information Disclosure Stmt	
Dependent Large Entity	Small Entity	8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
Fee Fee Code (\$)	Fee Fee Code (\$)	1809	770	2809	385	Filing a submission after final rejection	
1202 18	2202 9 Claims in excess of 20	l			005	(37 CFR § 1.129(a))	<u> </u>
1201 86 1203 290	2201 43 Independent claims in excess of 3 2203 145 Multiple dependent claim, if not paid	1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
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or number prev	iously paid, if greater; For Reissues, see above	*Reduce	ed by Basi	c Filing I	Fee Paid	SUBTOTAL (3) (\$)130	
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SUBMITTED BY Complete (if applicable)										
Name (Print/Type)	Nena Bains	Registration No. (Attorney/Agent)	47,400	Telephone	415-576-0200					
Signature	(h	N 0		Date	4115/04					

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BOX PATENT EXTENSION

Commissioner for Patents

Washington, D.C. 20231

TTC Docket No. 017516-007400US

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

Phillip S. Green

Patent No.:

5,808,665

Issued:

By:

September 15, 1998

Title: ENDOSCOPIC SURGICAL INSTRUMENT

AND METHOD FOR USE

#### REQUEST FOR RECONSIDERATION FOR FATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Hon. Commissioner of Patents and Trademarks

Box: Patent Extension Washington, D.C. 20231 RECEIVED

JAN 25 2002

Sir:

OFFICE OF PETITIONS Applicants respectfully request reconsideration for an extension of U.S. Patent No. 5,808,665. A patent term extension request was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration (hereinafter "FDA") approval of the da Vinci<sup>TM</sup> Robotic Surgery System. A Final Determination of Ineligibility (hereinafter "Determination") was mailed from the Patent Office on November 14, 2001.

Dismissal of the application for the subject patent term extension was apparently based on the determination by the Commissioner of Patents and Trademarks (hereinafter "Commissioner") that the da Vinci<sup>TM</sup> System underwent regulatory review under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (hereinafter "FFDCA"). Determination, page 2. However, as properly determined by the FDA, the da Vinci<sup>TM</sup> system was subjected to a regulatory review period as defined by 35 U.S.C. §156(a)(4), including regulatory review under section 515 of the FFDCA. FDA letter dated October 2, 2001.

Phillip S. Green Patent No.: 5,808,665

Page 2

The regulatory review of the da Vinci<sup>TM</sup> System was conducted under <u>both</u> sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k). As the da Vinci<sup>TM</sup> System was subjected to regulatory review under section 515, Applicants are entitled to a patent term extension. Per 35 U.S.C. §156(d)(2), the Secretary of Health and Human Services is responsible for determining the Regulatory Review Period for medical devices, and this matter was properly referred to the FDA. In a preliminary eligibility decision, the FDA informed the Commissioner that a "review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4)." *Id* (Emphasis added).

Reviewing the language of the statute, 35 U.S.C. § 156(a)(4), requires that, "the product has been subject to a regulatory review period before its commercial marketing or use." For medical devices, the term "regulatory review period" is defined in § 156(g)(3)(B) as follows:

- (i) the period beginning on the date a clinical investigation on human involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
- (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protoccl was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(Emphasis added). Therefore, within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regularory review period begins at the initiation of human clinical trials and ends on approval under the "Act," i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5.

The FDA correctly verified that Applicants meet the statutory requirements for a regulatory review period under the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B). *Id.* Specifically, Applicants began their first clinical investigations on humans on July 27, 1998. On January 17, 1999 Applicants submitted a section 510(k) application

Phillip S. Green Patent No.: 5,808,665

Page 3

#K990144 to the FDA seeking laparoscopic approval for its da Vinci<sup>TM</sup> System. On May 19, 1999, the FDA reclassified the da Vinci<sup>TM</sup> System into a class III device requiring Pre-Market Approval (hereinafter "PMA") under section 515. Applicants complied with the FDA mandated reclassification by (a) submitting a complete PMA application #P990079 on November 18, 1999 based on the same clinical data gathered during its earlier human clinical investigations, and (b) requesting that the FDA approve the da Vinci<sup>TM</sup> System under section 515 for laparoscopic procedures. The FDA accepted the PMA application for filing on November 29, 1999. On May 22, 2000, the FDA again reclassified the da Vinci<sup>TM</sup> System so that its corresponding PMA application #P990079, which had been reviewed for over a year under section 515, was reverted back to a 510(k). On July 11, 2000, the FDA approved the 510(k) application #K990144, with the submission date marked as November 18, 1999, the date the PMA application #P990079 under section 515 was submitted to the FDA.

As a final matter, Applicants gratefully acknowledge the Patent Office's correct determination that the Patent Term Extension request was timely filed. Determination, page 1. The FDA communication raised the issue as to whether the application was timely filed within the sixty-day (60) statutory period under 35 U.S.C. § 156(d)(1). FDA letter dated October 2, 2001. While the FDA often possesses information which is not readily available to the Commissioner, the Commissioner has primary responsibility for the eligibility determination. See M.P.E.P. § 2756. The Commissioner correctly determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms. Determination, page 1. The date of product approval was July 11, 2000. The present patent term extension application was filed on Monday, September 11, 2000. Sixty days after the approval date of the product was Saturday, September 9, 2000. 35 U.S.C. § 21(b) states that

When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

As Monday, September 11, 2000 was the next succeeding business day following the last day (Saturday, September 9, 2000), the application was timely filed.

As the FDA has verified that the present application satisfies the statutory

Phillip S. Green Patent No.: 5,808,665

Page 4

requirements for a regulatory review period under 35 U.S.C. § 156(a)(4) and the Commissioner has determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms, the last day of said sixty-day (60) period being September 11, 2000, the present application qualifies for a patent term extension. For the foregoing reasons, reconsideration and granting of Applicants application for patent term extension is respectfully requested.

Respectfully submitted,

David M. Shaw Reg. No. 38,688

Chief Patent Counsel Intuitive Surgical, Inc. Tel: (650) 237-7000

Fax: (650) 526-2060

PA 3191866 vI

PTO/SB/21 (08-00) Approved for use through 10/31/2002. OMB 0651-0031 1 9-1000se type a plus sign (+) inside this box -> + U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. 08/709,965 **Application Number** TRANSMITTAL. September 9, 1996 Filing Date **FORM** GREEN, Phillip S. First Named Inventor Group Art Unit (to be used for all correspondence after initial filing) **Examiner Name** 017516-007400US Attorney Docket Number Total Number of Pages in This Submission ENCLOSURES (check all that apply) After Allowance Communication to **Assignment Papers** Fee Transmittal Form Group (for an Application) Appeal Communication to Board of Drawing(s) Fee Attached Appeals and interferences Appeal Communication to Group Amendment / Response Licensing-related Papers (Appeal Notice, Brief, Reply Brief) ☐ Petition Routing Slip (PTO/SB/69) Proprietary Information After Final and Accompanying Petition Petition to Convert to a Status Letter Affidavits/declaration(s) Provisional Application Power of Attorney, Revocation Other Enclosure(s) Extension of Time Request Change of Correspondence Address (please identify below): Terminal Disclaimer Request for Reconsideration for Patent Express Abandonment Request Term Extension under 35 U.S.C §156 and Request for Refund Return Postcard Information Disclosure Statement CD, Number of CD(s) The Commissioner is authorized actor to Deposit Account 20-1430. Certified Copy of Priority Deposit Account 20-1430. Remarks Document(s) JAN 25 2002 Response to Missing Parts/ Incomplete Application OFFICE OF PETITIONS Response to Missing DEPUTY A/C PATENTS Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Townsend and Townsend and Crew LLP Firm and Reg. No. 36,443 Mark D. Barrish Individual name

CERTIFICATE OF MAILING

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PTO/SB/22 (10-00) Approved for use through 10/31/2002, OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Docket Number (Optional) TITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) 017516-007400US JAN 0 9 2002 In re Application of PHILLIP S. GREEN Filed September 9, 1996 Application Number 08/709,965 ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD Group Art Unit Examiner This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and appropriate non-small-entity fee are as follows (check time period desired): \$110 One month (37 CFR 1.17(a)(1)) ☐ Two months (37 CFR 1.17(a)(2)) ☐ Three months (37 CFR 1.17(a)(3)) Four months (37 CFR 1.17(a)(4)) Five months (37 CFR 1.17(a)(5)) Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown  $\boxtimes$ above is reduced by one-half, and the resulting fee is: \$ 55. A check in the amount of the fee is enclosed. Payment by credit card. Form PTO-2038 is attached. The Commissioner has already been authorized to charge fees in this application to a Deposit Account. The Commissioner is hereby authorized to charge any fees which may be required, RECEIVED
JAN 25 2002  $\boxtimes$ or credit any overpayment, to Deposit Account Number 20-1430. I have enclosed a duplicate copy of this sheet. I am the applicant/inventor. OFFICE OF PETITIONS assignee of record of the entire interest. See 37 CFR 3.71 Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96). attorney or agent of record. attorney or agent under 37 CFR 1.34(a). Registration number if acting under 37 CFR 1.34(a).

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January 9. 2002

Date

Signature

Mark D. Barrish, Reg. No. 36,443

Typed or printed name

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	Complete if Known	
Application Number	08/709,965	
Filing Date	September 9, 1996	
First Named Inventor	GREEN, Philip S.	
Examiner Name		
Group Art Unit		
Attorney Docket No.	017516-007400US	

		M	ETHO	OF PAYMENT						FEE C	ALCULATION (continued)	
The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:						3. At	3. ADDITIONAL FEES					
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Name							147	2,520	147	2,520	For filing a request for reexamination	
☐ Charge Any Additional Fee Required     Under 37 CFR 1.16 and 1.17						112	920*	112	920*	Requesting publication of SIR prior to Examiner action		
Applicant claims small entity status. See 37 CFR 1.27						113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action		
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			EEE C	ALCULATION			117	920	217	460	Extension for reply within third month	
1. BAS	IC FILI	ING FEE	-	ALCOLATION			118	1,440	218	720	Extension for reply within fourth month	
Large En	tity S	mall E	ntity				128	1,960	228	980	Extension for reply within fifth month	
Fee Fe			Fee	Fee Description			119	320	219	160	Notice of Appeal	
Code (\$)			(\$)		ſ	Fee Paid	120	320	220	160	Filing a brief in support of an appeal	
101 741	-		370	Utility filing ee			121	280	221	140	Request for oral hearing	
106 330 107 510			165 255	Design filing fee Plant filing fee			138	1,510	138	1,510	Petition to Institute a public use proceeding	
108 740	0 20	08 3	370	Reissue filing fee	• [		140	110	240	55	Petition to revive – unavoidable	
114 160	0 2	14 8	30	Provisional filing	fee		141	1,280	241	640	Petition to revive – unintentional	
			- <b></b>				142	1,280	242	640	Utility Issue fee (or reissue)	
		SUE	BTOTA	L (1)	Ł	(\$)	143	460	243	230	Designa issue (ee	
2. EXTRA C	CLAIM	FEES					144	620	244	310	(回じ)日本V LL	
					from	Fee	122	130	122	130	Petitions to the Commissioner	
Total Claims		20**	= [	Claims bel		Paid =	123	50	123	50	Retifions related to provisional applications 2002	
Independent Claims		-3**	=	×		=	126	180	126	180	Submission of Information Disclosure	
Multiple Dependent	<u> </u>	J ·	L			=	581	40	581	OF!	FICE OF PETITIONS Recording each patent assignment PETYPALOURA Turket as properties)	
	Entity Fee	Small Fee	Entit Fee				146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
	(\$) 18	Code 203	( <b>\$</b> ) 9	Fee Descript Claims in exc			149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))	
102	84	202	42	Independent of	laims in e	xcess of 3	179	740	279	370	Request for Continued Examination (RCE)	
	280	204	140	Multiple deper			169	900	169	900	Request for expedited examination	
		209	42	original paten	١.		Other	fee (speci	ifv\		of a design application	
110	18	210	9	over original p			The	Commissi	oner is a		ed to charge any additional fees to	
			s	UBTOTAL (2)	(\$)		the a	bove note	d Depo	sit Acco	unt.	
**or number	previous	sly paid, if	f greate	r; For Reissues, se	e above		*Red	luced by B	asic Filir	ng Fee P	aid SUBTOTAL (3) (\$)55	

SUBMITTED BY				Cor	mplete (if applicable)
Name (Print/Type)	Mark D. Barrish	Registration No. (Attorney/Agent)	36,443	Telephone	650-326-2400
Signature	1/4	232		Date	January 9, 2002

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